

REMARKS

Status of the Claims

Claims 36-51 are pending in this application.

Claims 36-51 stand rejected.

Claims 52-54 are newly added.

Claims 37, 41, 45 and 49 are canceled herein without prejudice or disclaimer.

Claims 36, 38, and 39 are amended herein.

New claim 52 specifies that the composition contains “about 1 wt% to about 3 wt% perilla oil based on total weight of the topical composition.” This range is supported by the application as filed at page 14, lines 15-22, wherein a broader range of “about 1 wt% to about 8 wt%” and the more narrow range of “about 3 wt% to about 6 wt%” are disclosed. The disclosure of the lower endpoint of the broader range (“about 1 wt%”) and the lower endpoint of the more narrower range (“about 3 wt%”) necessarily defines a range of “about 1 wt% to about 3 wt%” within the broader range. See In re Wertheim, 541 F.2d 257 (CCPA 1976).

Claims 53 and 54 have support in the specification at page 14, lines 3-5 and page 15, lines 9-12.

Accordingly, no new matter is introduced by way of this amendment.

Claim Rejections

35 U.S.C. § 112

Claims 36-51 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, and 35 U.S.C. § 112, second paragraph, as allegedly failing to set forth the subject matter which applicants regard as their invention. In each case, the rejections are based on the following passage from page 6, lines 7-13 of the specification:

It is surprising and unexpected that perilla oil inhibits upregulation by PPAR agonists, as perilla oil itself contains PPAR agonists such as linolenic acid and linoleic acid. This may be attributable to perilla oil undergoing oxidation on storage due to the high content of unsaturated fatty acids. The oxidation process may alter the PPAR stimulation activity of linolenic acid and linoleic acid, causing

the acids to bind to and shield the receptors, but not activate them, thereby preventing other agonists from reaching and activating the receptors.

The Examiner erroneously concludes from this passage that the “perilla oil must be ‘aged’ or ‘stored’ prior to obtaining PPAR activity” [OA, p. 5] and inasmuch as the claims do not require aged or stored perilla oil but “suggest instead that fresh perilla oil treats cellulite” [OA, p. 6], the Examiner contends that the claims lack written description and depart from what the applicants regarded as their invention. Applicants traverse these rejections.

Contrary to the Examiner’s statement that the perilla oil “must” be aged or stored, the cited passage does not even affirmatively indicate that storage or aging impacts the properties of the oil but instead merely speculates that the unexpected inhibitory activity “may” be attributable to oxidation on storage. Of course, this theory is not said to form any part of the invention and the patent laws do not require applicants to explain or even understand the science underlying an invention. The invention clearly was not intended to be limited to aged or stored perilla oil, as evidenced by the fact that: (i) applicants nowhere state that the invention requires aged perilla oil; (ii) the claims as originally filed recite perilla oil without reference to aging or storage; and (iii) Examples 1 and 2 of the instant application each disclose that perilla oil completely or significantly prevents PPAR upregulation in the presence of an agonist; there being no disclosure that the perilla oil used in those examples was aged or stored or comprised oxidized fatty acids. In short, nowhere is it stated in the application that the perilla oil must be aged or that the linolenic and linoleic acids must undergo oxidation to be effective.

The Examiner states that U.S. Patent No. 5,312,834 (“Yeo”) “teaches a composition of perilla oil for treating skin” and thus “should have the same activity, but the instant specification teaches that it does not.” (OA, p. 5). With respect to Yeo, the present application states that “Although Yeo teaches that perilla oil contains alpha-linolenic acid and fish oil contains eicosapentanoic acid, Yeo fails to teach or suggest that perilla oil would be effective to treat acne, absent the required ratio of eicosapentaenoic acid to alpha-linolenic acid.” (p. 3, Ins. 5-9). This is merely a statement that Yeo does not disclose any utility of perilla oil, alone, since Yeo’s compositions all require the combination with fish oil (eicosapentaenoic acid). Applicants fail to see how the Examiner construes this observation as a suggestion that the perilla oil of Yeo has not been aged or stored and thus has no activity.

The Examiner also states that there “exists no quantitative or measurable result of the ability of perilla oil to ‘improve the aesthetic appearance’ of skin affected by cellulite and

thus contends that the claim are indefinite. Applicants disagree with the Examiner's position and note that there have been numerous clinical studies made of record in this case where the appearance of cellulite-affected skin is objectively measured and that one skilled in the art would have no difficulty ascertaining whether the aesthetic appearance of cellulite is improved. Nevertheless, solely to advance prosecution of this case, this language ("amount effective to improve the aesthetic appearance") has been deleted from independent claim 36, which has been amended to include the weight range previously found in dependent claim 37.

Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. §112.

35 U.S.C. § 103

Claims 36-51 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 5,945,109 ("Schmidt") in view of U.S. Patent No. 5,312,834 ("Yeo"). The Examiner states that Schmidt discloses a "cosmetic product for topical administration for cellulite" which may comprise "essential oils and plant extracts" including "groundnut oil." The Examiner specifically points to Example 1 of Schmidt which discloses an anti-cellulite cream comprising 10% by weight "Hardened groundnut oil." The Examiner acknowledges that Schmidt does not disclose perilla oil but relies on Yeo as teaching "a composition comprising perilla oil." The Examiner contends that one skilled in the art would have been motivated to include perilla oil, as taught by Yeo, in the anti-cellulite creams of Schmidt because Yeo teaches that perilla oil "has no side effects" whereas groundnut oil is a "known allergen."¹ Applicants traverse this rejection.

Applicants submit that this rejection is improper for at least the reason that the Examiner has not offered a sufficient rationale as to why one skilled in the art would have been motivated to include perilla oil in Schmidt's anti-cellulite compositions. Yeo relates to a composition for treating acne which may comprise perilla oil. The perilla oil is said to be employed as a substitute for some of the fish oil since the perilla oil "exhibits the same effect as eicosapentaenoic acid of fish oil" but "has no side effects," whereas the fish oil "is decomposed in the body to produce toxic aldehydes such as malondialdehyde, which may cause side effects."

¹ To the extent that the Examiner is taking official notice of the alleged facts that "many people are known to have severe allergies to" groundnut oil, Applicants traverse this finding and request that the Examiner provide documentary evidence of the alleged fact. Traversal is on the grounds that the allergies to which the Examiner refers are to proteins in raw peanut oil, not to the oil itself, and that cosmetically suitable grades of groundnut oil for use according to the Schmidt patent would not comprise such allergens.

[col. 3, lines 32-48]. This limited teaching does not suggest using perilla oil in place of any other oil in any type of composition.

Moreover, Yeo's compositions are for oral delivery whereas the anti-cellulite compositions of Schmidt are topical. Specifically, Yeo teaches that the "composition of the present invention may be administered in the form of syrups or may be concentrated and filled in soft capsules." [col. 4, lines 49-51]. Further, Yeo states that "a satisfactory therapeutic effect can be obtained by administering one spoon (15 ml) of the composition every eight hours, three times a day." [col. 4, lines 60-66]. Thus, there is no teaching or suggestion in any of the cited art that perilla oil has topical efficacy against any condition, let alone cellulite.

Applicants submit that the Examiner has provided no rationale that would have motivated one skilled in the art to combine features of Yeo's oral acne medication with Schmidt's topical cellulite composition. Rather, Applicants respectfully submit that the Examiner is impermissibly engaging in hindsight based on Applicants own disclosure that perilla oil is effective at treating cellulite. Reconsideration and withdrawal of this rejection is requested.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

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